IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

STEVEN REID DOUGLAS and DANIELLE REID DOUGLAS,	:	**No. 3:23cv747**
Plaintiffs	:	**(Judge Munley)**
v.	:	
ATRIUM MEDICAL CORPORATION; MAQUET CARDIOVASCULAR US SALES, LLC; and GETTINGE AB,	:	
Defendants	:	

MEMORANDUM

Before the court for disposition is the Report and Recommendation ("R&R") issued by Magistrate Judge Martin C. Carlson on December 11, 2023 in this medical liability case involving implantable hernia mesh. (Doc. 40). The R&R makes recommendations with regard to the motions to dismiss filed by the defendants. Plaintiffs Steven Reid Douglas and Danielle Reid Douglas have filed objections to the R&R, and the matter is ripe for adjudication.

Background

The parties have not objected to the R&R's factual background, and therefore it will be adopted as follows:[1] This medical liability case involves *pro*

[1] This factual background section is taken from the R&R with minor editing and stylistic changes. (See Doc. 40 at 1-5). At this stage of the proceedings, the court must accept all

se husband and wife plaintiffs Steven Reid Douglas and Danielle Reid Douglas; and defendants Getinge AB ("Getinge"), a Swedish pharmaceutical corporation; Atrium Medical Corporation ("Atrium"), a medical device company; and Maquet Cardiovascular US Sales, LLC, a pharmaceutical company, and exclusive distributor of all surgical mesh products manufactured by the defendants. The plaintiffs aver that both Atrium and Maquet are wholly owned subsidiaries of Getinge.

The complaint alleges that on August 18, 2014, Steven Reid Douglas underwent implantation of ProLoop mesh to repair an inguinal hernia. ProLoop mesh is a product manufactured, marketed, and sold by the defendants. (Doc. 1, ¶ 38-39). Plaintiffs allege that immediately after the implantation of the ProLoop mesh, Steven Reid Douglas suffered a hernia recurrence and the onset of excruciating groin pain that continued for three years. (Id.) After undergoing a second surgery, it was discovered that the ProLoop mesh was in place around the cord, but a nerve was entrapped in the scar tissue, there was laxity of the tissues inferior to the inguinal ligament, and a defect in the femoral canal. (Id.) To reinforce the area, another type of mesh manufactured by the defendants,

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factual allegations in the complaint as true. Phillips v. Cnty. of Allegheny, 515 F. 3d 224, 233 (3d Cir. 2008). The court makes no determination, however, as to the ultimate veracity of these assertions.

ProLite, was implanted. (Id.) Douglas continued to experience nearly constant excruciating pain after the second surgery and underwent a third surgery on April 20, 2023. (Id. ¶ 40). During the third surgery it was discovered that the ProLoop and ProLite mesh had contracted and become surrounded by significant scar tissue. (Id. ¶ 41). The surgeon removed the scar tissue and a portion of the ProLoop and ProLite mesh but was unable to remove all the mesh due to the risk of disrupting blood supply and the potential for hernia reoccurrence, among other risks. (Id.) Douglas was given an ilioinguinal nerve block with Marcaine for pain and diagnosed with "[f]oreign body consistent with left inguinal mesh removal." (Id.)

The plaintiffs allege that the defective and negligent design and manufacture of the ProLoop and ProLite mesh that was implanted into his body, caused Stephen Reid Douglas to suffer permanent injury, despite the defendants' promotion of the mesh as safe and effective. Specifically, the plaintiffs allege that ProLoop and ProLite are made with polypropylene, a substance that is not biologically inert in the human body and can cause scar tissue to form around the mesh and the mesh to contract up to 50%, leading to long-term and even permanent complications. (Id. ¶¶ 15-18). In addition to the overall risks associated with polypropylene mesh, the plaintiffs also allege that ProLoop mesh specifically had design defects that made it particularly

dangerous, including looped filaments directly in contact with the walls of the hernia tract and a lack of bridging filaments between the loops, increasing the risk of mesh contracture and meshoma, and the product's unreasonably high volume of polypropylene. (Id. ¶ 32). Further, the plaintiffs allege that ProLoop was manufactured without antioxidant additives, despite Atrium being aware that polypropylene without antioxidants degrades faster than polypropylene which had been stabilized with antioxidant additives, increasing the risk of infection and pain. (Id. ¶ 33-36).

In sum, the plaintiffs argue that, despite the defendants' knowledge of the serious risks associated with the products, they promoted ProLoop and ProLite as safe treatments for hernia repair. As a result, Stephen Reid Douglas suffered permanent injuries, substantial excruciating pain and suffering, emotional distress, sexual dysfunction, medical expenses, lost wages and earning capacity, and diminished quality of life. (Id. ¶ 43). The complaint seeks to impute liability upon the defendants under the following claims: Count I - strict liability, design defect; Count II - strict liability, failure to warn; Count III – negligence; Count IV – breach of implied warranty; Count V – breach of express warranty; and Count VI – negligent misrepresentation. Plaintiff Danielle Reid Douglas sets forth a claim

for loss of consortium, Count VII.[2] The plaintiffs seek compensatory, punitive, and special damages, loss of earnings and earning capacity, medical expenses, and litigation expenses. (Doc. 40, R&R at 1 – 5)(footnote omitted).

Defendants Atrium Medical Corporation and Maquet Cardiovascular US Sales, LLC filed a motion to dismiss on July 10, 2023 pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. 19). Defendant Getinge AB filed a motion to dismiss for lack of jurisdiction and improper service on August 2, 2023 pursuant to Federal Rules of Civil Procedure 12(b)(2), 12(b)(5), and 12(b)(6). (Doc. 31). The R&R suggests the disposition of these motions. Plaintiffs have filed objections to the R&R's recommendation with regard to Count I and Count II. (Doc. 43). Neither party objects to the remainder of the R&R. The parties have briefed the objections, bringing the case to its present posture.

Jurisdiction

The court has jurisdiction pursuant to the diversity statute, 28 U.S.C. § 1332. Plaintiffs are citizens of Pennsylvania. (Doc. 1, ¶ 6). Defendant Atrium Medical Corporation is a citizen of Delaware and New Hampshire. (Id. ¶ 8). Defendant Maquet Cardiovascular US Sales is a citizen of Delaware and New Jersey (id. ¶ 9), and Defendant Getinge AB is a citizen of Sweden. (Id. ¶ 7).

[2] In an apparent drafting error, the complaint lists both negligent misrepresentation and loss of consortium as Count VI. For purposes of clarity, the court will refer to the latter of these counts, loss of consortium, as Count VII.

Additionally, the amount in controversy exceeds $75,000. (Id. Ad Damnum Cl. foll. ¶ 93). Because complete diversity of citizenship exists among the parties and the amount in controversy exceeds $75,000, the court has jurisdiction over this case. See 28 U.S.C. § 1332 ("district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between . . . citizens of different states[.]") As a federal court sitting in diversity, the substantive law of Pennsylvania shall apply to the instant case. Chamberlain v. Giampapa, 210 F.3d 154, 158 (3d Cir. 2000) (citing Erie R.R. v. Tompkins, 304 U.S. 64, 78 (1938)).

Legal Standard

Where no objections have been filed to an R&R, the court must determine if a review of the record evidences plain error or manifest injustice. If it does not then the court may adopt the R&R. FED. R. CIV. P. 72(b) 1983 Advisory Committee Notes ("When no timely objection is filed, the court need only satisfy itself that there is no clear error on the face of the record to accept the recommendation"); see also 28 U.S.C. § 636(b)(1).

The standard is different to portions of the R&R to which objections have been lodged. In disposing of objections to a magistrate judge's report and recommendation, the district court must make a *de novo* determination of those

portions of the report against which objections are made. 28 U.S.C. § 636(b)(1)(c); see also Sullivan v. Cuyler, 723 F.2d 1077, 1085 (3d Cir. 1983); Brown v. Astrue, 649 F.3d 193, 195 (3d Cir. 2011). The court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge. Henderson v. Carlson, 812 F.2d 874, 877 (3d Cir. 1987). The district court judge may also receive further evidence or recommit the matter to the magistrate judge with instructions. Id.

The R&R suggests the disposition of motions to dismiss. Defendants filed their motion to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The court tests the sufficiency of the complaint's allegations when considering a Rule 12(b)(6) motion. All well-pleaded allegations of the complaint must be viewed as true and in the light most favorable to the non-movant to determine whether, "'under any reasonable reading of the pleadings, the plaintiff may be entitled to relief.'" Colburn v. Upper Darby Twp., 838 F.2d 663, 665-66 (3d Cir. 1988) (quoting Estate of Bailey by Oare v. Cnty. of York, 768 F.2d 503, 506 (3d Cir. 1985)). The plaintiff must describe "'enough facts to raise a reasonable expectation that discovery will reveal evidence of' [each] necessary element" of the claims alleged in the complaint. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007)). Moreover, the plaintiff must allege facts that "justify moving the

case beyond the pleadings to the next stage of litigation." Id. at 234-35. In evaluating the sufficiency of a complaint the court may also consider "matters of public record, orders, exhibits attached to the complaint and items appearing in the record of the case." Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994) (citations omitted). The court does not have to accept legal conclusions or unwarranted factual inferences. See Curay-Cramer v. Ursuline Acad. of Wilmington, Del., Inc., 450 F.3d 130, 133 (3d Cir. 2006) (citing Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997)).

Discussion

The court will address all of the recommendations made by the R&R separately beginning with the issues raised by the motion to dismiss filed by Atrium Medical Corp. and Maquet Cardiovascular US Sales, LLC.

I. Motion to Dismiss Filed By Atrium Medical Corp. and Maquet Cardiovascular US Sales, LLC

The R&R discusses the first motion to dismiss by proceeding through the matter count by count. The court will do so also.

1. Count I and II

The R&R first addresses Count I and II which are based on the theory of strict products liability. Count I raises a strict products liability claim based upon a design defect and Count II is strict products liability based upon a failure to

warn. (Doc. 1, ¶¶ 45-51, 52-62). Plaintiffs have filed objections to the R&R regarding Counts I and II. Before addressing the objections, however, it is important to review the R&R's conclusions.

Pennsylvania has adopted the Restatement (Second) of Torts. Section 402A of the Restatement explains strict products liability where a seller sells a product in a defective or unreasonably dangerous condition. Webb v. Zern, 220 A.2d 853, 854 (Pa. 1966) (adopting the framework for strict products liability set forth at Section 402A of the Restatement (Second) of Torts). Comment k of Section 402A exempts a seller of an unavoidably unsafe product from strict liability where the product is "properly prepared and marketed, and proper warning is given, where the situation calls for it . . ." Restatement (Second) of Torts § 402A cmt. k. These products are exempted because "they are incapable of being made safe for their intended use, but are useful nonetheless." Creazzo v. Medtronic, Inc., 903 A.2d 24, 30 (Pa. Super. Ct. 2006).

The Pennsylvania Supreme Court has held that Comment k applies to prescription drugs, thus preventing strict products liability against manufacturers and sellers of such drugs. Hahn v. Richter, 673 A.2d 888 (Pa. 1996). The Pennsylvania Supreme Court has not yet addressed whether the reasoning set forth in Hahn applies so as to prohibit strict liability with regard to implantable medical devices such as are at issue here. The Pennsylvania Superior Court,

however, has held that Comment k does in fact bar strict liability claims in the medical device area. Creazzo, 903 A.2d at 30-31. Several courts within the Third Judicial Circuit have predicted that the Pennsylvania Supreme Court would extend the exemption to strict liability provided in Comment k to implantable medical devices. See McGrain v. C.R. Bard, Inc., 551 F. Supp. 3d 529, 537 (E.D. Pa. 2021); Wilson v. Synthes USA Prods., LLC, 116 F. Supp. 3d 463, 465-67 (E.D. Pa. 2015) (collecting cases); McPhee v. DePuy Ortho., Inc., 989 F. Supp. 2d 451, 461 (W.D. Pa. 2012); Ford v. St. Jude Med., LLC, No. 3:21cv1765, 2024 WL 4267981, at *5-6 (Sep. 23, 2024). The R&R finds the analysis provided by these cases from the Pennsylvania Superior Court and the district courts within the Third Circuit to be persuasive and that they suggest that under the current state of the law, plaintiffs' strict product liability claims are barred. The court agrees, and dismissal of Counts I and II is appropriate.

An added point that the court must address, however, is that the Third Circuit Court of Appeals certified a question to the Pennsylvania Supreme Court regarding the applicability of strict liability in implantable medical device cases. See Ebert v. C.R. Bard, Inc., No. 20-2139, 2021 WL 2656690, at *6 (3d Cir. Jun. 24, 2021).[3] The Pennsylvania Supreme Court accepted the certification.

[3] The certification process allows a federal court of appeals to ask the highest state court to rule on and clarify state law.

Subsequent to accepting the certification, however, Ebert settled and the Pennsylvania Supreme Court discontinued the case on November 9, 2021, before issuing a decision on the certified question. See Pa. Supreme Crt. Dkt. No. 26 EAP 2021. See also, Cohen v. Johnson & Johnson, 634 F. Supp. 3d 216, 224 (W.D. Pa. 2022) (explaining that the Ebert certification to the Pennsylvania Supreme Court has been discontinued).

The R&R suggests two possible ways to proceed, either: a) dismiss these counts without prejudice to renewal if the Pennsylvania Supreme Court rules favorably to plaintiffs in Ebert v. C.R. Bard, Inc., or b) defer a final ruling pending the decision in Ebert.

As the certification in Ebert was discontinued before a decision was issued, the court is only left with the option to dismiss Counts I and II with prejudice. Plaintiffs have filed objections to the R&R regarding Counts I and II. The objections do not object to the dismissal of these counts. Rather, plaintiffs have used their objections to seek permission to file an interlocutory appeal of the dismissal. After a careful review, the court will deny plaintiffs' request for an interlocutory appeal.

The law provides that a partial grant of a motion to dismiss[4] is not a final judgment, and thus is generally not appealable except by an interlocutory appeal under 28 U.S.C. § 1292(b). See FED. R. CIV. P. 54(b); see, e.g., Douris v. Schweiker, 229 F. Supp. 2d 391, 407–08 (E.D. Pa. 2002).

Whether or not to certify an interlocutory order for appeal under § 1292(b) "rests within the sound discretion of the trial court." Douris, 229 F. Supp. 2d at 408. "The burden is on the party seeking certification to demonstrate that 'exceptional circumstances justify a departure from the basic policy against piecemeal litigation and of postponing appellate review until after the entry of a final judgment.' " Id. (quoting Rottmund v. Cont'l Assurance Co., 813 F.Supp. 1104, 1112 (E.D. PA. 1992)).

Under § 1292(b), a district court may certify an interlocutory order for immediate appeal if it 1) "involves a controlling question of law," 2) there is "substantial ground for difference of opinion" as to the question of law, and 3) "an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b).

Here, the court finds that no substantial ground for difference of opinion as to whether plaintiffs' strict liability claims should be dismissed. As explained

[4] As addressed more fully below, the R&R does not suggest dismissal of all of plaintiffs' claims. Thus, the R&R recommends a partial grant of the motions to dismiss.

above, the appellate courts of Pennsylvania have ruled that the law supports dismissal. Additionally, district courts within this judicial district have also ruled that implanted medical devices are exempted from strict liability. Accordingly, the plaintiffs' request for interlocutory appeal will be denied.

2. Count III – Negligence

Count III of plaintiffs' complaint asserts a negligence cause of action. (Doc. 1, ¶¶ 63-68). Specifically, the complaint alleges that the "Defendants negligently, carelessly, recklessly and/or maliciously manufactured, designed . . . marketed . . . and sold ProLoop polypropylene mesh . . . " (Id. ¶ 65). Defendants have moved to dismiss this count. The R&R recommends the motion to dismiss Count III be denied. No objections have been filed to this recommendation, and review of the record does not evidence plain error or manifest injustice. See 28 U.S.C. § 636(b)(1). Therefore, this recommendation will be adopted and Count III will not be dismissed.

3. Count IV – Breach of Implied Warranty

Count IV of plaintiffs' complaint alleges a breach of implied warranty. (Doc. 1, ¶¶ 69-73). Defendants moved to dismiss this count, and plaintiffs conceded to dismissal of this claim in their sur-reply brief. (Doc. 30, at 4). Accordingly, the motion to dismiss Count IV will be granted.

4. Count V– Breach of Express Warranty

Count V of plaintiffs' complaint asserts a cause of action for breach of express warranty. (Doc. 1, ¶¶ 74-77). The R&R recommends dismissal of Count V without prejudice to plaintiffs submitting an amended complaint that details the specific source of any express warranty and any specific statements made by the defendants, beyond the marketing of the device as safe. No objections to this recommendation have been filed and a review of the record does not evidence plain error or manifest injustice. See 28 U.S.C. § 636(b)(1). Therefore, this recommendation will be adopted and Count V will be dismissed without prejudice.

5. Count VI – Negligent Misrepresentation

Count VI of the complaint asserts a cause of action for negligent misrepresentation. (Doc. 1, ¶¶ 78-84). The R&R recommends dismissing Count VI without prejudice to the plaintiffs amending their complaint to include specific overt acts or affirmative misrepresentations made by the defendants that go beyond a failure to warn. (Doc. 40, at 24). No objections to this recommendation have been filed and a review of the record does not evidence plain error or manifest injustice. 28 U.S.C. § 636(b)(1). Therefore, this recommendation will be adopted and Count VI will be dismissed without prejudice.

6. Count VII – Loss of Consortium and Punitive Damages

Plaintiffs' complaint also raises a loss of consortium claim on behalf of Plaintiff Danielle Reid Douglas. (Doc. 1, ¶¶ 85-88). Additionally, the complaint seeks punitive damages. (Id. ¶¶ 89-93). Defendants moved to dismiss both the loss of consortium claim and the punitive damages claim. The R&R suggests that the motion to dismiss these claims be denied. No objections to this recommendation have been lodged and a review of the record does not evidence plain error or manifest injustice. See 28 U.S.C. § 636(b)(1). Therefore the motion to dismiss will be denied with regard to the loss of consortium claim and the punitive damages claim.

II. Defendant Getinge AB's motion to dismiss

The court now turns to Defendant Getinge AB's motion to dismiss which raises issues of personal jurisdiction and service of the complaint.

1. Defendant Getinge's Motion To Dismiss – Personal Jurisdiction

Defendant Getinge separately moved to dismiss plaintiffs' complaint pursuant to Rule 12(b)(2) of the Federal Rules of Civil Procedure. One of the grounds for dismissal raised by Defendant Getinge is that the court lacks personal jurisdiction over it. The R&R recommends denying the motion to dismiss for lack of personal jurisdiction without prejudice to the defendant renewing the motion after the completion of discovery. No objections to this recommendation have been lodged and a review of the record does not evidence

plain error or manifest injustice. See 28 U.S.C. § 636(b)(1), Therefore Defendant Getinge's motion to dismiss for lack of personal jurisdiction will be denied without prejudice to renewal of the motion after discovery is completed.

2. Defendant Getinge's Motion To Dismiss – Improper Service

Defendant Getinge's motion also seeks dismissal of the complaint on the basis that the plaintiffs did not properly serve the complaint. The R&R concludes that the evidence fails to show that plaintiffs made proper service upon Defendant Getinge. Instead of dismissing the case, however, the R&R suggests that a reasonable prospect exists that service may yet be obtained. Accordingly, the magistrate judge's recommendation is that the court should quash service, leaving the plaintiffs free to effect proper service. Further, based upon the plaintiffs' *pro se* status, the magistrate judge recommends that the court direct plaintiffs to obtain a proper address for the corporate headquarters, or any registered agent for receipt of service of process, and instruct the plaintiffs to seek service through United States Marshals. The record reveals no objection to these recommendations, and they shall therefore be adopted. See 28 U.S.C. § 636(b)(1).

Conclusion

For the reasons set forth above, Magistrate Judge Carlson's R&R will be adopted. An appropriate order follows.

Date: 9/30/24

JUDGE JULIA K. MUNLEY
United States District Court